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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,349	10/15/2003	Graham Nigel Maw	PC10343C	1852

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PFIZER INC.
PATENT DEPARTMENT, MS8260-1611
EASTERN POINT ROAD
GROTON, CT 06340

EXAMINER	
KANTAMNENI, SHOBHA	
ART UNIT	**PAPER NUMBER**
1617	

NOTIFICATION DATE	DELIVERY MODE
09/19/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

~IPGSGro@pfizer.com

Office Action Summary	Application No.	Applicant(s)	
	10/686,349	MAW ET AL.	
	Examiner	Art Unit	
	Shobha Kantamneni	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30-35 and 37-67* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *NONE* is/are allowed.

6)☒ Claim(s) *30-35 and 37-67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *03/06/2008;01/31/2005;10/15/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 30-35, and 37-67 are pending.

Election/Restrictions

Applicant's election of invention Group I, claims 30-35, 37-67 drawn to a method of treating a female suffering from female sexual dysfunction comprising the step of delivering to a female a therapeutically effective amount of a neuropeptide Y inhibitor, wherein the female sexual dysfunction is female sexual arousal disorder in the reply filed on 10/18/2007, is herein acknowledged.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). The requirement is made FINAL.

Claims 30-35, and 37-67 are examined herein on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 31, 33-34, 39-46, 50, 52-53, and 58-65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The expression “said inhibitor has a selective effect on the genitalia of said female" in claims 31, 50 “said neuropeptide Y is a mediator of genital vasorelaxation” in

claims 33, 52, “wherein said neuropeptide Y inhibitor is a mediator of vaginal or clitoral vasorelaxation” in claims 34, 53, “wherein said inhibitor has a Ki value” as in claims 39-46, 58-65 renders the claim indefinite as to what NPY inhibitors are encompassed by the claims. What NPY inhibitors are considered as NPY inhibitors that “have a selective effect on the genitalia of said female", that “mediate genital vasorelaxation”, that “mediate vaginal or clitoral vasorelaxation”. And what NPY inhibitors will not “have a selective effect on the genitalia of said female", that “mediate genital vasorelaxation”, that “mediate vaginal or clitoral vasorelaxation”? Also which of the NPY inhibitors will have a Ki value as in claims 39-46, and 58-65, and which of the NPY inhibitors will not have a Ki value as in claims 39-46, and 58-65. In other words, the metes and bounds of the claims are not defined.

Claims 47, and 66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "pharmaceutically active agent" in claims 47, and 66, renders the claims indefinite as to what compounds are encompassed by the claims. It is not clear what naturally occurring and synthetic molecules are encompassed by the recitation "pharmaceutically active agent" in the claims herein. The instant specification pages 26-27, recites some pharmaceutically active agents such as PDE5 inhibitor, dopamine receptor agonist, one or more heterocyclic amine etc. It is not clear what "pharmaceutically active agent" family is referred to in the instant Case. Further, only a

few well-known PDE5 inhibitors, dopamine receptor agonist are listed in the instant specification. It is unclear to one of ordinary skill in the art what other compounds are considered as "pharmaceutically active agent", since a vast number of compounds would have been encompassed herein. For example, heterocyclic amine can be any compound having an amine group and a cyclic ring having a hetero atom such as O, S, N etc. which can include thousands of compounds. Thus, it is not clear what compounds are encompassed herein by the recitation "pharmaceutically active agent". In other words, the metes and bounds of the claims are not defined.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 30-35, 37-46, 48-65, and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hutchison et al. (WO 98/03492, PTO-1449), and further in view of Gregor et al. (WO 98/07420, PTO-1449), and as evidenced by Tejada (US 6,277,884, PTO-892).

Hutchison et al. teaches a new class of neuropeptide Y1 specific ligands. Hutchison et al. also teaches a method of treating disorders associated with an inappropriate stimulation of neuropeptide Y receptors, including diseases related to

sexual dysfunction and reproductive disorders, and abnormal drink and food intake such a obesity, anorexia, bulimia, and metabolic disorders (See page 9, lines 6-9 and 26-28 in particular). Hutchison et al. teaches the composition comprising the Neuropeptide Y1 antagonist is useful for oral, topical, parenteral administration (See page 11, lines 3-4).

Gregor et al. teaches compound F50 of the instant application as regulators of NPY activity. See page 15, page 60, and abstract in particular. Gregor et al. further teaches that these compositions, which possess vasodilating activities and are capable of beneficially affecting the reperfusion of ischemic organs, can be administered orally, topically and locally. See page 19, lines 3-5 and 11-20, in particular.

Tejada teaches that vasodilators are known to treat sexual dysfunction such as female sexual arousal disorder in female. See abstract; column 10, lines 42-67. Tejada teaches administration of N-hydroxyguanidine compounds, and pharmaceutically acceptable salts thereof in the method of treating female sexual arousal disorder.

The references do not expressly teach the neuropeptide Y inhibitors can treat female arousal disorder. The references do not teach the herein claimed timing of dosing (.e., before or during sexual arousal).

One of ordinary skill in the art at the time of invention would have been motivated to administer the neuropeptide Y inhibitors of Hutchison et al. or Gregor et al. in a method of treating female sexual arousal disorder because the neuropeptide Y inhibitors of Hutchison et al. or Gregor et al. are known to possess vasodilating activities and are capable of beneficially affecting the reperfusion of ischemic organs to increase the blood flow perfusion, and as evidenced by Tejada, vasodilators treat sexual arousal

disorder. Accordingly, one of ordinary skill in the art at the time of invention would have been motivated to administer neuropeptide Y inhibitors of Huchison et al. Gregor et al. with reasonable expectation of success of treating female sexual arousal disorder. Examiner notes that F50 is the exemplified neuropeptide Y inhibitors and therefore considered as possessing the herein claimed characteristics i.e., "NPY inhibitor has a selective effect on the genitalia", as in claims 31, 50, "Wherein in the absence of sexual stimulation the inhibitor has no or negligible effect in causing an increase in genital blood flow", as in claims 32, 51, "where said amount of neuropeptide Y inhibitor delivered causes potentiation of cAMP" as in claims 37-38, and 56-57, and the Ki values recited in instant claims 39-46, and 58-65.

One of ordinary skill in the art would have been motivated to administer the NPY inhibitors of Hutchison and Gregor in the treatment of female sexual arousal disorder before or during sexual arousal. Optimization of dosage regimen is considered as within the purview of skilled artisan.

Claims 47, and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hutchison et al. (WO 98/03492, PTO-892), in view of Gregor et al. (WO 98/07420, PTO-1449), and as evidenced by Tejada (US 6,277,884, PTO-892) as applied to claims 30-35, 37-46, 48-65, and 67 above.

Hutchison et al., Gregor et al., and Tejada are applied as discussed above.

Hutchicon et al. does not specifically teach administration of NPY inhibitor in combination of another pharmaceutically active agent in the method of treating sexual dysfunction.

It would have been obvious to a person of ordinary skill in the art at the time of invention to administer N-hydroxyguanidine compound in combination with NPY inhibitor to treat sexual dysfunction because Tejada teaches that N-hydroxyguanidine compounds are known to treat female sexual arousal disorder. One of ordinary skill in the art at the time of invention would have been motivated to administer N-hydroxyguanidine compounds in combination with NPY inhibitor with reasonable expectation of success of obtaining at least additive effect in the method of treating sexual dysfunction in women.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shobha Kantamneni whose telephone number is 571-272-2930. The examiner can normally be reached on Monday-Friday, 8am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shobha Kantamneni
Patent Examiner
Art Unit : 1617

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1617